NOVARTIS AG
Form 6-K
August 28, 2007

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 or 15d-16 OF**

**THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated August 27, 2007**

**(Commission File No. 1-15024)**

# Novartis AG

**(Name of Registrant)**

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

**Form 20-F: x** Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No: x**

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No: x**

**Novartis International AG**
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

**- Investor Relations Release -**

## Rasilez® receives EU approval, the first major innovation in high blood pressure treatment for more than a decade

- *A direct renin inhibitor, Rasilez is the first medicine to directly target the source of high blood pressure*
- *Alone or in combination with other medicines, Rasilez provides significant blood pressure lowering for 24 hours and beyond(1)-(4)*
- *Nearly half of adults in Europe s largest countries suffer from high blood pressure(5), which can cause heart attack, stroke and death(6)*
- *Strong need for new therapies since nearly 70% of high blood pressure patients still not achieving treatment goals(6),(7)*

**Basel, August 27, 2007** Rasilez® (aliskiren), the first new type of high blood pressure medicine in more than a decade, has been approved for use in the European Union. Nearly half of all adults in Europe s largest countries, such as Germany, Italy and the UK, suffer from this potentially life-threatening condition(5).

The European Commission approved Rasilez for the treatment of high blood pressure alone or in combination with other high blood pressure medicines, based on data from more than 7,800 patients in 44 clinical trials. The approval applies to all 27 EU member states plus Iceland and Norway.

Rasilez is the first medicine to directly target high blood pressure at its source, the enzyme renin, said Dr. Roland Schmieder, Professor of Medicine at the University of Erlangen-Nuremberg, Germany. As doctors, our biggest challenge is getting blood pressure under control in the first place and then keeping it there. Because Rasilez works well alone or with other medicines, it shows good promise in helping patients, even those who haven t yet achieved control with other medicines.

Experts estimate that nearly one billion people globally have high blood pressure and that nearly 70% of these people do not reach healthy blood pressure levels(6),(7). As a result, they live at risk of complications like heart attack, stroke, kidney failure, blindness and death, creating a strong need for new high blood pressure therapies(6).

Rasilez is the first in a new class of medicines called direct renin inhibitors. It acts by directly inhibiting renin, an enzyme that triggers a process that can lead to high blood pressure. This new

medication received its first approval in March 2007 from the US Food and Drug Administration under the brand name Tekturna®, and has also been approved in Switzerland.

When used alone, Rasilez demonstrates greater blood pressure lowering than other commonly-used blood pressure medicines like angiotensin converting enzyme (ACE) inhibitors(8) and the diuretic hydrochlorothiazide (HCT)(9).

For patients already taking other medicines, but not at their blood pressure goal, Rasilez provides additional blood pressure lowering when added to existing therapy. This additional benefit is seen when Rasilez is added to ACE inhibitors(10), angiotensin II receptor blockers (ARBs)(3), calcium channel blockers (CCBs)(11) or HCT(12), while offering a placebo-like tolerability profile(3).

Rasilez consistently lowers blood pressure for 24 hours and beyond(1),(2). This is an important treatment consideration, because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges.

Direct renin inhibition is the only major innovation in treating high blood pressure for more than a decade, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Rasilez is the first approved medicine that helps patients reach their blood pressure goal by controlling the renin system. Novartis is proud to bring this important new medicine to the fight against this damaging and rapidly increasing disease.

The long-term potential of Rasilez and direct renin inhibition is being studied in a clinical program known as ASPIRE HIGHER, focusing on the benefits of using Rasilez in high blood pressure patients with heart failure or kidney failure. Data from the program are expected to be released later this year.

High blood pressure and its consequences is the world s No. 1 cause of death. This condition, also called hypertension, occurs when the blood in the body moves through the blood vessels at a higher pressure than normal and causes damage to the arteries, kidneys, brain and other vital organs that can ultimately lead to heart failure.

Rasilez was developed in collaboration with Speedel.

**Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as can , potentially , promise , estimate , potential , expected , or similar expressions, or by express or implied discussions regarding potential future revenue from Rasilez. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez will reach any particular sales levels. In particular, management s expectations regarding Rasilez could be affected by, among other things unexpected clinical trial results, including additional analysis of clinical data, or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; increased government, industry, and general public pricing pressures; our ability to obtain or maintain patent or other proprietary intellectual property protection; and other risks and factors referred to in Novartis AG s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-

looking statements contained in this press release as a result of new information, future events or otherwise.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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**Novartis Media Relations**

**Corinne Hoff**
Novartis Global Media Relations
+41 61 324 9577 (direct)
+41 79 248 5717 (mobile)
corinne.hoff@novartis.com

**Peter Shelby**
Novartis Pharma Communications
+41 61 324 4470 (direct)
+41 79 597 6353 (mobile)
peter.shelby@novartis.com

e-mail: media.relations@novartis.com

**Novartis Investor Relations**

**International**
**Ruth Metzler-Arnold**
Katharina Ambuehl
Nafida Bendali
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis

Central phone no: +41 61 324 7944
e-mail: investor.relations@novartis.com

**North America**

| | |
|---|---|
| **Ronen Tamir** | +1 212 830 2433 |
| Jill Pozarek | +1 212 830 2445 |
| Edwin Valeriano | +1 212 830 2456 |

e-mail: investor.relations@novartis.com

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: August 27, 2007

By: /s/ Malcolm B. Cheetham

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting